WHEN CHANGING ONE WORD CAN SAVE A LIFE: BARE INSTEAD OF ELUTING.

I would like to add some comments and challenge the established authorities (stent producers, medical academic professionals, FDA regulators and also medical insurance companies) to reconsider the usage and undertake additional research in the direction toward the improvement of bare metal stents.

In the last two decades, stents, which are used in over 90% of percutaneous coronary interventions revolutionized balloon angioplasty by cutting the rate of post procedure restenosis. This tremendous reduction was again cut in recent years by using drug-eluting stents. It seemed that the perfect solution had been reached, but unfortunately this was only an illusion. Some researchers and practitioners (1) cautioned their concern about the long-term outcome of drug eluting stents almost from the beginning of their approval by the FDA, recommending them only for high-risk patient and for very specific vessels. Recently those concerns have started to resonate more strongly as more detailed data arrives “BASKET”(2), BASKET-LATE”(3). These trials suggest that the unrestrictive and overwhelming use of DES has created a trade-off, between late restenosis versus death or main health hazard by late thrombosis. Even the primary stent producer Boston Scientific recently acknowledged the greater risk of late stent thrombosis from usage of their Taxus DES stents(4). All of these events concerning DES influenced FDA to hold this public meeting(5).

I write these comments both as an inventor and as a potential future recipient of stents (eighteen months ago I underwent quintuple coronary bypass surgery). When it comes to human health I, like everyone else have the unquestionable right to demand the best available treatment, which in this cases mean the best stent.

As an inventor, for the last several years I have worked on improvement of metallic surfaces towards better bio- and heamocompatibility. I came up with a patent pending process, which I call “magnetoelectropolishing”. The main advantage of this process over standard electropolishing used as finishing step in production of BMS is the profound improvement of surface wettability (about 25% for 316L stainless steel and even more for Nitinol). According to a lot of research, more wettable metallic surfaces are more thromboresistant (there is good guidewire data to support this(6)) and also more favorable to faster and more complete integration with contacted tissue(7). Some thromboresistivity tests have shown the superiority of “magnetoelectropolished “ 316l stainless steel surfaces over standard electropolished ones(8). The hypothesis is that more wettable metallic surfaces are more hydrated when they come in contact with blood and that this factor is probably responsible for minimizing protein adsorption and conformation, which eventually minimizes platelets adhesion, leading to better thromboresistivity. I have reason to suspect that metallic surfaces with increased wettability could be more favorable to faster and more perfect endothelization, which consequently should lead to minimization of in stent restenosis.

I challenge stent producers, medical academic professionals, FDA regulators and medical insurance companies to rethink DES problems and worked on BMS improvement for the health benefits of stent recipients and also for cost reduction.

Maybe the old saying “More expensive does not mean better” will prove itself once again and the often used phrase “next generation of DES” will be replaced by “next generation of BMS” with better results.

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Ryszard Rokicki
ELECTROBRIGHT
142 W. Main St.
Macungie, Pa 18062
Phone (610) 967-5800
Email info@electrobright.com